

Rec'd 1/21/2005 HDS



541 Apollo Court
Vallejo, CA 94591
(707) 332-8366
stimulights007@aol.com

To: F.D.A Attn: Dale Smith
Center of Devices & Radiological Health
2098 Gaither Road
Rockville, Maryland 20805
Fax# (204) 276-0129

Dear Sir/Madam,

I James Donaldson, owner of Stimulights Lasers in Vallejo, California am requesting a renewal of my expired variance license which was issued in 2001. My F.D.A. Docket number is: 01A1468. I am also submitting my annual Laser Light Show reports for the duration of my valid variance period. I would also like to mention that I recently provided a laser light show in Tucson, Arizona and received an inspection by the Arizona State Radiology Department preformed by Mr. John Lamb at the event in which I was providing a laser light show at. I received this event at the last minute and I did not properly follow the correct procedures for notifying your department and the State of Arizona. I provided lasers at this event with an expired variance. The day of the show I Faxed you department and the Arizona Department of Radiology my show report form. I understand that I have made a bad decision for operating Lasers with an expired Variance license and not notifying the proper departments prior to this event. I would like to apologize to your department and I wish to have the opportunity to renew my license and follow all guidelines the F.D.A. and State departments have. This is a business in which I love and am good at. I do not want to further ruin my chances to be the best Legal Laser Light Show company in the United States. I am 100% dedicated to follow all rules. Please consider my request for a renewal of my Laser Variance License. You may reach me for any questions at the telephone number or e-mail address.

Thank you for your consideration,

James Donaldson /Owner
Stimulights Lasers

OIV-D328

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